

IN THE SPECIFICATION

Page 1, immediately following the title, insert the following text:

--This is a continuation of copending parent application 09/799,251, filed March 5, 2001.--

Page 2, first full paragraph, amend as follows:

--In contrast with such beneficial effects, long-term use of estrogens is positively correlated with an increased risk for endometrial cancer development. This risk may be reduced by simultaneous administration of a progestin, which prevents overgrowth of endometrial cells. Hence, an estrogen/progestin combined HRT protocol is recommended for a woman with an intact uterus. This form of combination therapy however, apparently diminishes the beneficial effects of estrogen on the plasma lipid profile (Lobo R. 1992. The Role of Progestins in Hormone Replacement Therapy; Am. J Obstet. Gynecol. 166:1997-2004). Furthermore, some progestins are associated with an increased risk of mammary cancer development (Staffa J. A. et al. ~~1991~~ 1992. Progestins and Breast Cancer: An Epidemiologic Review, 57:473-491; King R.J.B. 1991. A Discussion of the Roles of Estrogen and Progestin in Human Mammary Carcinogenesis, J. Ster. Biochem. Molec. Bio. ~~39:8111-8118~~ 39:811-818) .--

Paragraph spanning pages 3 and 4, amend as follows:

--A phytoestrogen concentration range of approximately 0.1 to 2-3  $\mu$ M is representative of that found in healthy, both Asian and European, with soy-based diets.

(Adlercreutz,, H. et al. 1993. Plasma Concentrations of Phytoestrogens in Japanese Men, Lancet 342:1209-1210; Gooderham et al., 1996. A Soy Protein Isolate Rich in Genistein and Daidzeina dn its Effects on Plasma Isoflavone Concentrations, Platelet Aggregation, Blood Lipids and Fatty Acid Composition of Plasma Phospholipid in Normal Men, J. Nutr. ~~125:2000-2006~~ 126:2000-2006). At these lower concentrations, various phytoestrogens, including genistein, coumestrol, biochanin A, apigenin, luiolin, kaempferl and entrolactone, were shown to induce cell proliferation in estrogen receptor-positive, but not in estrogen receptor negative human breast cancer cell lines, thus demonstrating the estrogenic effects of these compounds (Wang, C. and ~~Kurtzer~~ Kurzer, M.SW. 1997.

Phytoestrogen concentration Determines Effects on DNA synthesis in Human Breast Cancer Cells, Nutr. Cancer 28:236-247).--

Page 5, first full paragraph, amend as follows:

--Lycopene, a carotenoid found in tomatoes, is strongly associated with anti-oxidant and anti-cancer activities. The anti-proliferation effects of lycopene on breast cancer cells *in vitro* has been shown to be mediated

through interference with the IGF-1 receptor signaling pathway and cell cycle progression (Karas et al. 2000. Lycopene interferes with cell cycle progression and insulin-like growth factor I signaling in mammary cells. Nutr. Cancer, 36:101-11). IGF-I is a growth factor obligatory for malignant transformation of breast tissue, and its concentration in plasma determines risk factor for cancers of both the breast (LeRoith, D., Werner, H., Beitner-Johnson, D. and Roberts, C.T., Jr. 1995. Molecular and cellular aspects of the insulin-like growth factor I receptor. Endocr. Rev. ~~16:143-59~~ 16:143-63; Hankinson S.E. et al. 1998. Circulating concentrations of insulin-like growth factor-I and risk of breast cancer. Lancet 351:1393-6) and prostate (Chan, J. M., Stampfer, M.J. Giovannucci, E., Gann, P.H., Ma, J. 1998 Plasma insulin-like growth factor-I and prostate cancer risk: a prospective study. Science 279:563-66).